

REMARKS

Previously, Claims 1, 3-9, 12-16, 18, 29, 34, 35, 37 and 42 were pending and under consideration and Claims 10, 11, 17, 20-27, 44 and 54-56 were withdrawn. In the instant amendment, Claims 10, 11 and 20-27 have been canceled, without prejudice as explained below. Claims 1, 6, 29, and 37 have been amended. Claim 57 has been added. After entry of the instant amendment, Claims 1, 3-9, 12-16, 29, 34, 35, 37, 42 and 57 will be pending and under consideration.

I. AMENDMENT TO THE SPECIFICATION

The specification has been amended to include a proper priority benefit claim. Applicants submit herewith a Petition to Accept an Unintentionally Delayed Claim for Priority under 37 C.F.R. § 1.78. It is respectfully requested to enter the amendment to the specification.

II. AMENDMENTS TO THE CLAIMS

Claims 10, 11 and 20-27 have been canceled as being drawn to nonelected subject matter. Claims 1, 29 and 37 have been amended to delete nonelected subject matter. Applicants reserve the right to prosecute nonelected subject matter in one or more other applications.

Claim 6 has been amended to depend from Claim 5.

New Claim 57 has been added. Claim 57 is drawn to a ApoA-I agonist compound which is a D-enantiomeric peptide of SEQ ID NO:4. Support for newly added Claim 57 can be found, for example, on page 44, lines 22-31, on page 73, line 12 and on page 75, line 1.

No new matter has been introduced with the instant amendments to the claims. Entry of the amendments to the claims is respectfully requested.

No claim fee is believed to be due.

III. RESTRICTION/ELECTION REQUIREMENT

Applicants' reply mailed August 19, 2004, to the Restriction Requirement included a typographical error. Claim 17, and not Claim 18 as stated in the reply, reads on elected species of SEQ ID NO:4 (PVLDLFRELLNELLEALKQKLK). As discussed by telephone between Examiner Celsa and Roger Rich on March 31, 2005, it is Applicants' understanding that this inadvertent error resulted in the withdrawal of Claim 17 in the Office Action mailed October 28, 2004. Applicants respectfully request that Claim 17 be re-entered for

consideration. Further as discussed over the telephone, it is Applicants' understanding that Claim 18 is withdrawn, without prejudice to Applicants' right to have Claim 18 rejoined should a generic claim encompassing the compounds recited in Claim 18 be found allowable.

Applicants acknowledge that process claims of Groups VI (claims 44 and 55-56 (in part)) and VII (claims 54 and 55-56 (in part)) can be rejoined in accordance with M.P.E.P. § 821.04 once product claims of Group I are allowed. Applicants reserve the right to rejoin Claims 44, 54, 55 and 56 currently withdrawn from consideration.

IV. NONSTATUTORY DOUBLE PATENTING

A. U.S. Patent No. 6,046,166 in view of Garber et al.

Claims 1, 3-6, 9, 12, 13, 16, 18 and 37 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-49 of U.S. Patent No. 6,046,166 in view of Garber *et al.* (1992) *Arteriosclerosis & Thrombosis* 12: 886-894. Without acquiescing with the propriety of the rejection and in order to expedite prosecution, Applicants respectfully request that the rejection be withdrawn in view of the Terminal disclaimer and fee filed herewith.

B. U.S. Patent No. 6,329,341 in view of Garber et al.

Claims 1, 3-9, 12-16, 18 and 37 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-21 of U.S. Patent No. 6,329,341 ("the '341 patent") in view of Garber *et al.* Applicants respectfully traverse.

Obviousness-type double patenting is a judicially created doctrine intended to prevent improper timewise extension of the patent right by prohibiting the issuance of claims in a second patent which are not "patently distinct" from the claims of a first patent. *See In re Braat*, 19 U.S.P.Q.2d 1289, 1291-92 (Fed. Cir. 1991).

Applicants respectfully submit that Claims 1-21 of the '341 patent are patentably distinct from Claims 1, 3-9, 12-16, 18 and 37 of the instant application. Claims 1-21 of the '341 patent recite methods of treating septic shock using apolipoprotein A-I peptides or peptide analogs. In the restriction requirement mailed June 23, 2004, in the instant application, the Patent Office itself states that Group I (the elected group) is *patentably distinct* from Group VII (methods of treatment of septic shock). For this reason alone, the rejection is improper. Further, the claimed compounds also differ in that they are "D" peptides, not a mixture or "L" peptides.

The Patent Office cites Garber *et al.* to allege that it would be obvious to one of

ordinary skill in the art to modify D-amino acids for L-amino acids in certain peptides. However, the authors in Garber *et al.* do *not* teach or suggest why it is obvious to one of ordinary skill in the art to modify the peptides recited in the claims of the '341 patent to arrive at the subject matter in instant Claims 1, 3-9, 12-16, 18 and 37. Indeed, Garber *et al.* merely studies the physical properties of certain specific rat apolipoproteins and says nothing about the peptides disclosed herein. Moreover, the reference says nothing about the activity of the "D" versus "L" rat peptides that were studied by Garber *et al.* Instead, they merely comment on one pharmacokinetic property. This falls well short of providing the legally required reasonable expectation of success needed for an obviousness based rejection. See *In re Dow*, 5 U.S.P.Q.2d 1529, 1531-1532 (Fed. Cir. 1988). Therefore, claims drawn to methods of treating septic shock using "L" apolipoprotein A-I peptides do not render claims drawn to "D" apolipoprotein A-I peptides obvious. Accordingly, Applicants respectfully request that the rejection of Claims 1, 3-9, 12-16, 18 and 37 under the judicially created doctrine of obviousness-type double patenting be withdrawn.

C. U.S. Patent No. 6,376,464 in view of Garber et al.

Claims 1, 3-9, 12-16, 18, 29, 34, 35, 37 and 42 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 2-18 of U.S. Patent No. 6,376,464 ("the '464 patent") in view of Garber *et al.* Applicants respectfully traverse.

Applicants respectfully submit that Claims 2-18 of the '464 patent are patentably distinct from Claims 1, 3-9, 12-16, 18, 29, 34, 35, 37 and 42 of the instant application. Claims 2-18 of the '464 patent recite peptide:lipid complexes comprising apolipoprotein A-I "L" peptides and lipids. The instant application claims apolipoprotein A-I peptides alone. Further, the claimed compounds also differ in that they are "D" peptides, not a mixture or "L" peptides. Therefore, the scope of claims in the '464 patent and the instant application is different.

The Patent Office cites Garber *et al.* to allege that it would be obvious to one of ordinary skill in the art to modify D-amino acids for L-amino acids in certain peptides. However, the authors in Garber *et al.* do *not* teach or suggest why it is obvious to one of ordinary skill in the art to modify the peptide:lipid complexes comprising apolipoprotein A-I "L" peptides recited in the claims of the '464 patent to arrive at the subject matter in instant Claims 1, 3-9, 12-16, 18, 29, 34, 35, 37 and 42. Indeed, Garber *et al.* merely studies the physical properties of certain specific rat apolipoproteins and says nothing about the peptides

disclosed and claimed herein. Moreover, the reference says nothing about the activity of the “D” versus “L” rat peptides that were studied by Garber. Instead, they merely comment on one pharmacokinetic property. This falls well short of providing the legally required reasonable expectation of success needed for an obviousness based rejection. *See In re Dow*, 5 U.S.P.Q.2d 1529, 1531-1532 (Fed. Cir. 1988). Therefore, claims drawn to peptide:lipid complexes comprising apolipoprotein A-I “L” peptides do not render claims drawn to “D” apolipoprotein A-I peptides alone obvious. Accordingly, Applicants respectfully request that the rejection of Claims 1, 3-9, 12-16, 18, 29, 34, 35, 37 and 42 under the judicially created doctrine of obviousness-type double patenting be withdrawn.

D. U.S. Patent No. 6,518,412 in view of Garber et al.

Claims 1, 3-9, 12-16, 18 and 37 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-9 of U.S. Patent No. 6,518,412 (“the ’412 patent”) in view of Garber *et al.* Applicants respectfully traverse.

Obviousness-type double patenting is a judicially created doctrine intended to prevent improper timewise extension of the patent right by prohibiting the issuance of claims in a second patent which are not “patentably distinct” from the claims of a first patent. *See In re Braat*, 19 U.S.P.Q.2d 1289, 1291-92 (Fed. Cir. 1991). In *General Foods Corp. v. Studiengesellschaft Kohle mbH*, the Federal Circuit further explained that in an obviousness-type double patenting rejection “it is important to bear in mind that comparison can be made only with what invention is *claimed* in the earlier patent, paying careful attention to the rules of claim interpretation to determine what invention a claim *defines* and not looking to the claim for anything that happens to be mentioned in it as though it were a prior art reference.” *See, e.g., General Foods Corp.*, 23 U.S.P.Q.2d 1839, 1845 (Fed. Cir. 1992). Applicants respectfully submit that the Patent Office is mistaken concerning what is claimed in Claims 1-9 of the ’412 patent, and by not considering what the claims of the ’412 patent define, the Patent Office arrives at a legally improper double patenting rejection of Claims 1, 3-9, 12-16, 18 and 37.

The Patent Office states that the ’412 patent “claims ApoA-I agonist peptide compounds.” These claims, in fact, recite *nucleotide sequences* (or host cells expressing a peptide encoded by a recited nucleotide sequences) that *encode* peptides comprised of L-amino acids. The subject matter of the instant claims are compounds comprising D-amino acids.

The Patent Office cites Garber *et al.* to allege that it would be obvious to one of ordinary skill in the art to modify the claimed subject matter in the '412 patent to arrive at the subject claimed in the instant application. However, the authors in Garber *et al.* do *not* teach or suggest, nor does the Patent Office provide any explanation, of how the *nucleotide sequences* recited in the claims of the '412 patent could encode D-amino acids. *See, e.g., General Foods Corp.*, 23 U.S.P.Q.2d at 1845 (stating that the trial court was in error for looking at whatever a claim *discloses*, but not at what invention it *defines*). Applicants respectfully submit that Claims 1, 3-9, 12-16, 18 and 37 are patentably distinct over the Claims 1-9 of the '412 patent in view of Garber *et al.*, and request that the rejection of the instant claims under the judicially created doctrine of obviousness-type double patenting be withdrawn.

E. U.S. Patent No. 6,573,239 in view of Garber et al.

Claims 1, 3-9, 12-16, 18, 29, 34, 35, 37 and 42 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-34 of U.S. Patent No. 6,573,239 ("the '239 patent") in view of Garber *et al.* Applicants respectfully traverse.

Obviousness-type double patenting is a judicially created doctrine intended to prevent improper timewise extension of the patent right by prohibiting the issuance of claims in a second patent which are not "patentably distinct" from the claims of a first patent. *See In re Braat*, 19 U.S.P.Q.2d 1289, 1291-92 (Fed. Cir. 1991).

Claims 1-34 of the '239 patent recite compounds, complexes and compositions comprising a peptide wherein one or two helical turns are deleted from formula (I), *inter alia*. In the Restriction Requirement mailed June 23, 2004, in the instant application, the Patent Office itself states that Group I (the elected group) is *patentably distinct* from Group II (deletion analogs of formula (I)). For this reason alone the rejection is improper. Further, the claimed compounds also differ in that they are "D" peptides, not mixture or "L" peptides.

The Patent Office cites Garber *et al.* to allege that it would be obvious to one of ordinary skill in the art to modify D-amino acids for L-amino acids in certain peptides. However, the authors in Garber *et al.* do *not* teach or suggest, nor does the Patent Office provide any explanation, of why it is obvious to one of ordinary skill in the art to modify the deleted forms of formula (I) peptides recited in the claims of the '239 patent to arrive at the subject matter in instant Claims 1, 3-9, 12-16, 18, 29, 34, 35, 37 and 42. Indeed, Garber *et al.* merely studies the physical properties of certain specific rat apolipoproteins and says nothing

about the peptides disclosed herein. Moreover, the reference says nothing about the activity of the “D” versus “L” rat peptides that were studied by Garber *et al.* Instead, they merely comment on one pharmacokinetic property. This falls well short of providing the legally required reasonable expectation of success needed for an obviousness based rejection. *See In re Dow*, 5 U.S.P.Q.2d 1529, 1531-1532 (Fed. Cir. 1988). Therefore, claims drawn to compounds, complexes and compositions comprising an “L” peptide wherein one or two helical turns are deleted from formula (I) do not render claims drawn to full-length “D” apolipoprotein A-I peptides obvious. Applicants respectfully request that the rejection of Claims 1, 3-9, 12-16, 18, 29, 34, 35, 37 and 42 under the judicially created doctrine of obviousness-type double patenting be withdrawn.

F. U.S. Patent No. 6,630,450 in view of Garber et al.

Claims 1, 3-9, 12-16, 18, 29, 34, 35, 37 and 42 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-36 of U.S. Patent No. 6,630,450 (“the ‘450 patent”) in view of Garber *et al.* Applicants respectfully traverse.

Applicants respectfully submit that Claims 1-36 of the ‘450 patent are patentably distinct from Claims 1, 3-9, 12-16, 18 and 37 of the instant application. Claims 1-36 of the ‘450 patent recite methods of treating dyslipidemic disorders using apolipoprotein A-I peptides or peptide analogs. In the restriction requirement mailed June 23, 2004, in the instant application, the Patent Office itself states that Group I (the elected group) is *patentably distinct* from Group VI (methods of treatment of dyslipidemia). For this reason alone, the rejection is improper. Further, the claimed compounds also differ in that they are “D” peptides, not a mixture or “L” peptides.

The Patent Office cites Garber *et al.* to allege that it would be obvious to one of ordinary skill in the art to modify D-amino acids for L-amino acids in certain peptides. However, the authors in Garber *et al.* do *not* teach or suggest why it is obvious to one of ordinary skill in the art to modify the peptides recited in the claims of the ‘450 patent to arrive at the subject matter in instant Claims 1, 3-9, 12-16, 18 and 37. Indeed, Garber *et al.* merely studies the physical properties of certain specific rat apolipoproteins and says nothing about the peptides disclosed herein. Moreover, the reference says nothing about the activity of the “D” versus “L” rat peptides that were studied by Garber *et al.* Instead, they merely comment on one pharmacokinetic property. This falls well short of providing the legally required reasonable expectation of success needed for an obviousness based rejection. *See In*

re Dow, 5 U.S.P.Q.2d 1529, 1531-1532 (Fed. Cir. 1988). Therefore, claims drawn to methods of treating dyslipidemia using “L” apolipoprotein A-I peptides do not render claims drawn to “D” apolipoprotein A-I peptides obvious. Accordingly, Applicants respectfully request that the rejection of Claims 1, 3-9, 12-16, 18, 29, 34, 35, 37 and 42 under the judicially created doctrine of obviousness-type double patenting be withdrawn.

G. U.S. Application No. 10/802,080 in view of Garber et al.

Claims 1, 3-9, 12-16, 18, 29, 34, 35, 37 and 42 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-36 of co-pending application 10/802,080 in view of Garber *et al.* Applicants respectfully request that the rejection be held in abeyance until either of the applications is allowed. *See* MPEP 804(I)(B).

H. U.S. Application No. 10/283,599 (U.S. Pat. No. 6,844,327) in view of Garber et al.

Claims 1, 3-9, 12-16, 18, 29, 34, 35, 37 and 42 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-68 of co-pending application 10/283,599 in view of Garber *et al.* Application no. 10/283,599 issued January 18, 2005, as U.S. Patent No. 6,844,327 (“the ’327 patent”) and has 23 claims. Applicants respectfully traverse.

As stated in Section IV.D above, the Federal Circuit explained in *General Foods Corp. v. Studiengesellschaft Kohle mbH*, that in an obviousness-type double patenting rejection “it is important to bear in mind that comparison can be made only with what invention is *claimed* in the earlier patent, paying careful attention to the rules of claim interpretation to determine what invention a claim *defines* and not looking to the claim for anything that happens to be mentioned in it as though it were a prior art reference.” *See General Foods Corp.*, 23 U.S.P.Q.2d 1839, 1845 (Fed. Cir. 1992).

The Patent Office states that the ’327 patent claims *disclose* compounds, complexes and compositions. In fact, the ’327 patent defines an isolated nucleic acid in Claim 1, and the remaining claims depend from Claim 1. Garber *et al.* is cited by the Patent Office to allege that it would be obvious to one of ordinary skill in the art to modify the claimed subject matter in the ’327 patent to arrive at the subject matter recited in the instant claims. The authors in Garber *et al.* do *not* teach or suggest, nor does the Patent Office provide any explanation, of how the nucleic acid recited in the claims of the ’327 patent could encode

D-amino acids. *See, e.g., General Foods Corp.*, 23 U.S.P.Q.2d at 1845 (stating that the trial court was in error for looking at whatever a claim *discloses*, but not at what invention it *defines*). Indeed, Garber *et al.* merely studies the physical properties of certain specific rat apolipoproteins and says nothing about the peptides disclosed herein. Moreover, the reference says nothing about the activity of the “D” versus “L” rat peptides that were studied by Garber *et al.* Instead, they merely comment on one pharmacokinetic property. This falls well short of providing the legally required reasonable expectation of success needed for an obviousness based rejection. *See In re Dow*, 5 U.S.P.Q.2d 1529, 1531-1532 (Fed. Cir. 1988). Therefore, claims drawn to a nucleic acid do not render claims drawn to “D” apolipoprotein A-I peptides obvious. Applicants respectfully submit that Claims 1, 3-9, 12-16, 18, 29, 34, 35, 37 and 42 are patentably distinct over Claims 1-23 of the ’327 patent in view of Garber *et al.*, and request that the rejection of the instant claims under the judicially created doctrine of obviousness-type double patenting be withdrawn.

I. U.S. Application No. 10/099,574 in view of Garber et al.

Claims 1, 3-9, 12-16, 18, 29, 34, 35, 37 and 42 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-55 of co-pending application 10/099,574 in view of Garber *et al.* Applicants respectfully request that the rejection be held in abeyance until either of the applications is allowed. *See MPEP 804(I)(B).*

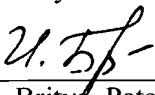
CONCLUSION

In light of the above amendments and remarks, Applicants respectfully request that the Patent Office reconsider this application with a view towards allowance.

The Commissioner is hereby authorized to charge any required fee(s) to Jones Day Deposit Account No. 50-3013 (referencing Attorney Docket No. 9196-022-999).

Respectfully submitted,

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